5. 510(K) SUMMARY K082016 AUG 10 2009

**510(k) SUMMARY**
**(per 21 CFR §807.92)**

**GDx with ECC Retinal Nerve Fiber Layer Normative Database**

## GENERAL INFORMATION

| | |
|---|---|
| Manufacturer: | Carl Zeiss Meditec Inc.<br>5160 Hacienda Drive<br>Dublin, California 94568<br>(925) 557-4616 (phone)<br>(925) 557-4481 (fax)<br>Est. Reg. No. 2918630 |
| Contact Person: | Judith A. Brimacombe, MA<br>Director, Regulatory/Clinical Affairs<br>Carl Zeiss Meditec Inc.<br>5160 Hacienda Drive<br>Dublin, California 94568<br>(925) 557-4616 (phone)<br>(925) 557-4481 (fax) |
| Classification name: | Ophthalmoscope |
| Classification: | Class II (acc. 21 CFR 886.1570) |
| Product Code: | MYC, HLI |
| Trade/Proprietary name: | GDx with ECC Retinal Nerve Fiber Layer Normative Database |

## PREDICATE DEVICE

| | |
|---|---|
| Company: | Carl Zeiss Meditec, Inc. |
| Device: | Nerve Fiber Analyzer (K941705) |
| Company: | Carl Zeiss Meditec, Inc. |
| Device: | Stratus OCT (K030433) |

## INTENDED USE

The GDx is a confocal polarimetric scanning laser ophthalmoscope that is intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo. The GDx and its GDx Variable Corneal Compensation (VCC) and GDx Enhanced Corneal Compensation (ECC) RNFL Normative Databases aid in the diagnosis and monitoring of diseases and disorders of the eye that may cause changes in the polarimetric retinal nerve fiber layer thickness. The GDx is to be used in patients who may have an optic neuropathy.

## DEVICE DESCRIPTION

The GDx with ECC Retinal Nerve Fiber Layer Normative Database is a confocal scanning laser ophthalmoscope comprising an opto-mechanical scanning laser head unit and a computer. The device employs Scanning Laser Polarimetry (SLP) to measure the Retinal Nerve Fiber Layer (RNFL) thickness using polarized light.

## SUBSTANTIAL EQUIVALENCE

The GDx with ECC Retinal Nerve Fiber Layer Normative Database is substantially equivalent to the predicate devices identified previously. The GDx with ECC Retinal Nerve Fiber Layer Normative Database is substantially equivalent to the predicate devices with regards to intended use, operating principle, function, and materials.

Clinical evaluation performed on the GDx supports the expanded indications for use statement and demonstrates the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness with respect to ophthalmoscopes.

## CLINICAL EVALUATION

A clinical study was conducted at ten sites to gather data for the ECC normative database, to train the nerve fiber indicator (NFI), and to compare two GDx algorithms, variable corneal compensation (VCC) and enhanced corneal compensation (ECC).

The GDx ECC RNFL thickness normative database was created using GDx ECC scan data from 251 subjects, 18 to 82 years of age, who were deemed representative of the normal population. The normative database has an even distribution of right and left eyes, as well as gender, and has a wide representation of the general population with regard to refractive error, intraocular pressure, axial length, corneal curvature and thickness measurement spectrum.

Data from 215 subjects with early, moderate and late stage glaucoma were also collected for the purpose of training the ECC NFI. Two-thirds of the normal and

glaucoma study eyes were randomly selected by statistical programs as the model building subset for the development of the ECC NFI. The other one-third of the study eyes was used for model validation.

Results revealed that the ECC and VCC algorithms correlated well, and their ability to measure the RNFL thickness was similar. The ECC algorithm generated a lower atypical scan rate than the VCC algorithm and the ECC algorithm compensated for the anterior segment birefringence better than the VCC algorithm.

## SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on the GDx with ECC Retinal Nerve Fiber Layer Database to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Carl Zeiss Meditec Incorporated
c/o Judith A. Brimacombe, M.A.
Director, Clinical/Regulatory Affaires
5160 Hacienda Drive
Dublin, CA 94568

AUG 10 2009

Re: K082016
Trade Name: GDx VCC with ECC
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC, HLI
Dated: June 4, 2009
Received: June 9, 2008

Dear Ms. Brimacombe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K082016

Device Name: GDx with ECC Retinal Nerve Fiber Layer Normative Database

Indications for Use:

The GDx is a confocal polarimetric scanning laser ophthalmoscope that is intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo. The GDx and its GDx Variable Corneal Compensation (VCC) and GDx Enhanced Corneal Compensation (ECC) RNFL Normative Databases aid in the diagnosis and monitoring of diseases and disorders of the eye that may cause changes in the polarimetric retinal nerve fiber layer thickness. The GDx is to be used in patients who may have an optic neuropathy.

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

8/7/2009

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K082016